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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,673	06/05/2002	Gunther Beisel	FI-37PCT	9183
7590 07/15/2004				
Friedrich Kueffner 317 Madison Avenue Suite 910 New York, NY 10173				
EXAMINER TRAN, SUSAN T				
ART UNIT		PAPER NUMBER		
1615				

DATE MAILED: 07/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,673	BEISEL, GUNTHER	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>002404 3-6-02</u> | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Receipt is acknowledged of applicant's Change of Address filed 09/09/02, and Information Disclosure Statement filed 03/06/02.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 4-6 recite the limitation "the compound" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim. It is unclear what compound? Claim 1 does not recite any compound.

Regarding claims 10 and 11, the phrases "preferably " and "particularly preferably" render the claim indefinite because it is unclear whether the limitations following the phrases are part of the claim or just exemplary.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The claims are drawn to a composition comprising sponge-like structure coated with a compound. Sponge-like is interpreted as foam, sponge, cellulose, or any liquid retaining/absorbing materials.

Claims 1-8 and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Cromarty US 3,688,763.

Cromarty discloses a gelatin capsule comprising compressible sponge (abstract). The gelatin capsule is enterically coated with cellulose acetate phthalate and is made of material that is enzyme degradable (column 1, lines 34-40; and column 2, lines 15-20). Cromarty further teaches the compressible sponge is chosen with a view to easy compressibility, and must be inert to the action of fluids present in the intestines, such as polyurethane sponge (column 2, lines 9-14). The sponge is compressed inside the shells to its one quarter of its original size (column 1, lines 62 through column 2, lines 1-5).

It is noted that Cromarty does not expressly teach that the enteric coating soluble in liquid having a pH of 5-10 (claims 5-7). However, such limitation is clearly inherent because Cromarty teaches the use of the same enteric coating compound disclosed in applicant's specification at page 6, namely, cellulose acetate phthalate. Furthermore, Cromarty discloses the enteric capsule is remains unchanged and unaffected in the stomach, but dissolve in the small intestine. It is well known in pharmaceutical art that pH in a small intestine ranging from about 5 to about 8 (see Kurihara et al. at column 3, lines 5-8 for reference). Accordingly, the enteric coating taught by Cromarty is inherently soluble in liquid having the claimed pH.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cromarty.

Cromarty is relied upon for the reason stated above. It would have been obvious for one of ordinary skill in the art to modify the enteric capsule of Cromarty to obtain the claimed invention with the expectation of providing a capsule comprising sponge with an enteric coating so that the capsule does not degrade in a patient stomach.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kajs et al. US 5,397,573, in view of Ratjen et al. US 5,603,950.

Kajs teaches a laxative composition comprising capsule containing cellulose, starch, binder and/or gelatin materials (column 4, lines 3-68 through column 5, lines 1-5). The capsule is enterically coated (column 2, lines 25-30).

Kajs does not teach cellulose capsule in the form of sponge or foam.

Ratjen teaches gelatin capsule comprising cellulose material in the form of sponge (columns 1-2). Thus, it would have been obvious for one of ordinary skill in the art to modify the cellulose capsule of Kajs using the cellulose sponge in view of the teaching of Ratjen with the expectation of providing a gelatin capsule filled with non-toxic substance for the treatment of constipation.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kurihara et al., Meer et al., Fara et al., Hird et al., and Rhodes et al. are cited as of interest for the teachings of capsule comprising cellulose and/or sponge materials.

Correspondence


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600